

[CHAPTER 613]

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act of June 25, 1938, as amended, by providing for the certification of batches of drugs composed wholly or partly of insulin, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 301 (i) of the Federal Food, Drug, and Cosmetic Act, of June 25, 1938, as amended, is amended by inserting "506," before the phrase "or 604." at the end thereof.

SEC. 2. Section 502 of such Act, as amended, is amended by inserting a new paragraph at the end thereof, as follows:

"(k) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 506, and (2) such certificate or release is in effect with respect to such drug."

SEC. 3. Chapter V of such Act, as amended, is amended by adding a new section at the end thereof, as follows:

"CERTIFICATION OF DRUGS CONTAINING INSULIN

"SEC. 506. (a) The Federal Security Administrator, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of insulin. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Administrator prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Administrator, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

"(b) Regulations providing for such certification shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe no standard of identity or of strength, quality, or purity for any drug different from the standard of identity, strength, quality, or purity set forth for such drug in an official compendium.

"(c) Such regulations, insofar as they prescribe tests or methods of assay to determine strength, quality, or purity of any drug, different from the tests or methods of assay set forth for such drug in an official compendium, shall be prescribed, after notice and opportunity for revision of such compendium, in the manner provided in the second sentence of section 501 (b). The provisions of subsections (e), (f), and (g) of section 701 shall be applicable to such portion of any regulation as prescribes any such different test or method, but shall not be applicable to any other portion of any such regulation."

December 22, 1941
[H. R. 6251]
[Public Law 366]

Federal Food, Drug,
and Cosmetic Act,
amendments.
52 Stat. 1042.
21 U. S. C. § 331 (i).

52 Stat. 1050.
21 U. S. C. § 352.

Misbranded insulin.

Infra.

52 Stat. 1049.
21 U. S. C. § 351-355.

Certification of
drugs containing in-
sulin.

Release in lieu of
certification.

Regulations pre-
scribing standards,
etc.

Different tests or
methods of assay.

52 Stat. 1049.
21 U. S. C. § 351 (b).

52 Stat. 1055.
21 U. S. C. §§ 371
(e)-371 (g).

Promulgation of regulations.

SEC. 4. Regulations initially prescribed under section 506 of such Act, as amended, shall be promulgated and made effective within forty-five days after the date of enactment of this Act.

Approved, December 22, 1941.

[CHAPTER 617]

AN ACT

December 22, 1941
[S. 1623]
[Public Law 367]

To suspend the export tax and the reduction of the quota prescribed by section 6 of the Act of March 24, 1934 (48 Stat. 456), as amended, for a fixed period, and for other purposes.

Philippine Islands.
Suspension of export
tax for period ending
Dec. 31, 1942.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the imposition and collection of the export tax prescribed by section 6 of the Act of March 24, 1934, entitled "An Act to provide for the complete independence of the Philippine Islands, to provide for the adoption of a constitution and a form of government for the Philippine Islands, and for other purposes" (48 Stat. 456), as amended by the Act of August 7, 1939 (53 Stat. 1226; U. S. C., Supp. V, title 48, sec. 1236), shall be suspended for a period commencing on and after the date following the approval of this Act and ending on December 31, 1942.

48 U. S. C. § 1236.

Resumption.

On January 1, 1943, the imposition of such export tax shall be resumed, the tax rate effective for said calendar year to be the same as the rate in effect at the time the tax was suspended; on each succeeding January 1 thereafter the export tax shall be increased progressively by an additional 5 per centum of the United States duty, except that during the period January 1, 1946, through July 3, 1946, the export tax shall remain at 15 per centum of the United States duty.

Suspension of reduction of quotas of certain articles.

53 Stat. 1227.
48 U. S. C. § 1236
(b) (3).

SEC. 2. That the progressive reduction of the quotas of the Philippine articles of a class or kind in respect of which a quota is established by subdivision 3, subsection b, section 6 of the said Act of March 24, 1934, as amended, shall be suspended for a period commencing on and after the date following the approval of this Act and ending on December 31, 1942; the original quotas established by that subdivision for the year 1940 shall be in effect during the suspension.

Resumption.

On January 1, 1943, the progressive reduction of the quotas provided for in subdivision 3, subsection b, section 6 of the said Act of March 24, 1934, as amended, shall be resumed, the rate of reduction effective for said calendar year to be the same as the rate in effect at the time the said quotas were suspended; for each calendar year thereafter through the calendar year 1945, each of the said quotas shall be the same as the corresponding quota for the immediately preceding calendar year, less 5 per centum of the corresponding original quota.

Quotas for period in 1946.

For the period January 1, 1946, through July 3, 1946, each of said quotas shall be one-half of the corresponding quota specified for the calendar year 1945.

SEC. 3. Nothing in this Act shall change in any respect not herein expressly provided for the provisions of the Act of March 24, 1934, as amended.

Approved, December 22, 1941.